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Biosafety of Genetically Modified Organisms in the Latin American and the Caribbean Region: Main Needs and Opportunities for Strategic Capacity Building

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Biotechnology has the potential to help improve food production in Latin America and the Caribbean (LAC), a continent where agriculture plays a dominant role in peoples' lives and in trade. It is therefore critical that recombinant DNA (rDNA) biotechnology is regulated in such a manner as to capture its benefits and to minimize any potential risks. In order to best understand biosafety needs in LAC, an email-based stakeholder consultation was carried out, augmented by personal communications with well-informed respondents, and integrated into a desktop study incorporating information from recent peer-reviewed literature. The resultant qualitative study tracked developments in rDNA biotechnology and biosafety in the region and reviewed regulatory capacity as well as the legacies of previous capacity-building projects in these areas to culminate in a snapshot of the present situation. It demonstrated that approximately half of the 31 countries represented in the study are not carrying out any domestic research and development on genetically modified organisms (GMOs); furthermore, the majority have not developed GM products beyond the proof-of-concept stage. Only 58% of the study countries appear to have operational biosafety regulatory systems in place. Acknowledging that methods of delivering capacity building should be tailored to specific demand-driven needs, the study identified possible knowledge and expertise gaps in the region, to be used as a basis for possible training and/or support interventions.

Key words: biosafety, genetically modified organisms (GMOs), capacity building, research and development (R&D), Latin America and the Caribbean (LAC).

Introduction

Investment in agricultural research and development (R&D) has contributed to economic growth and poverty reduction in the Latin America and the Caribbean (LAC) region over the past 50 years (International Assessment of Agricultural Knowledge, Science, and Technology for Development [IAASTD], 2008; World Bank, 2008). Nevertheless, the specific potential of biotechnology R&D in improving food production needs has yet to be fully exploited in a continent where 510 million people live, approximately 27 million of whom survive on less than US$1 per day (Stads & Beintema, 2009). The increasing adoption of genetically modified (GM) crops around the globe (James, 2010), along with the implementation of the Cartagena Protocol on Biosafety (CPB; Secretariat of the Convention on Biological Diversity [CBD], 2000), have made it imperative for countries to act promptly to define and implement policy in biosafety (Araya-Quesada, Degrassi, Ripandelli, & Craig, 2010; Johnston, Monagle, Green, & Mackenzie, 2008). Moreover, recognizing that institutional and scientific capacities in many countries are often insufficient to meet their international requirements, the CPB also calls for capacity building to help member countries to comply.

Similar to other parts of the world, the introduction and development of products resulting from the use of recombinant DNA (rDNA)[1] biotechnology in some countries of the LAC region has generated wider continental concerns surrounding the possible risks and unintended effects that might arise, which is a situation that obstructs the development of local regulatory policies, legislation, and GM products in many parts. Moreover, those concerns directly related to biodiversity are of par-

1. *rDNA biotechnology encompasses those techniques that result in transgenic, genetically modified (GM), or genetically engineered (GE) organisms.*

ticular importance. The LAC region has been acknowledged as the most biologically diverse on the planet, comprising several of the world's megadiverse countries (United Nations Environmental Programme [UNEP], 2010). In addition, the region hosts the center of origin of many globally important crop species, such as cassava, cocoa, common bean, maize, potato, sweet potato, and tomato (Trigo, Traxler, Pray & Echeverría, 2002).

Presently, many countries in LAC cultivate GM crops. Brazil recently became the second-placed country (behind the United States) in the world in terms of GM crop hectarage, with Argentina a close third (James, 2010). However, the local use of rDNA biotechnology for commercial purposes is still at an early stage, resting primarily upon having sufficient scientific capacity, the willingness to adopt the technology, and the availability and/or prioritizing of economic resources. To this end, every country in the region is challenged to develop public-sector research capacity and appropriate regulatory frameworks to access new knowledge and opportunities (Trigo et al., 2002).

Currently, several biosafety issues are specifically being addressed in LAC, including environmental safety, food safety, socio-economic impacts, and regulatory aspects. Consequently, regulatory capacity needs to be enhanced in order to provide countries with the necessary tools not only to decide whether they wish to assess and apply rDNA biotechnology, but also how to do so appropriately. To date, this capacity is inhibited in many countries of the region due to the absence of coherent regulatory instruments and institutions to undertake risk assessment and management, as well as insufficient numbers of suitably-trained personnel and the non-availability of requisite scientific information. There are also vast differences in terms of biosafety proficiency amongst countries in the region, and as such, there has been no consensus on how best to react to global developments in genetic engineering and, particularly, whether to permit the importation and/or development of GM products.

Furthermore, any capacity-building initiative aiming to provide support towards the autonomy of biosafety regulatory systems in the region should acknowledge that there are no ready solutions and that a careful analysis and identification of needs and current competences should be performed (Araya-Quesada et al., 2010). It was therefore with this foremost in mind, that the present study was undertaken.

Material and Methods

A database of more than 300 people intimately involved in biosafety and/or biotechnology activities in the region was constructed. Contacts mainly came from National Competent Authorities [NCAs], universities, CPB focal points, government ministries, capacity-building initiatives, research centers, and non-governmental organizations. Email-based survey forms were distributed to each contact from late 2009 to early 2010, with an update in April 2011. The survey forms were sent in both Spanish and English to cover the two major languages spoken in the region. It included questions of two types: those provided with multiple-choice answers to obtain specific or quantifiable information (e.g.: Are GMOs regulated in your country? Are there any GMOs authorized in your country? Is/will a cost-benefit analysis be performed during the risk analysis?) and open questions where the respondent was free to compose their reply (e.g.: Which scientific data do you consider is lacking for the risk assessment? How will a cost-benefit analysis be performed under the decision-making process?). Data collected included, *inter alia*, the status of national biosafety regulatory systems; the technical expertise of NCA personnel; locally-identified training needs; former training opportunities; as well as current in-country activities involving the production, development, and/or commercialization of GMOs. To this end, surveys were sent to all 33 countries in the region.

Data returned by correspondents were then collated, summarized, and supplemented with information from news reports, peer-reviewed publications, available internet resources, and follow-up personal communications with key stakeholders during the latter part of 2010 and early 2011. The same supplementary information-gathering methods were also used to describe the situation in countries which lacked a responding contact (see Table 1). Furthermore, when conflicting or inconsistent answers were received, a clarification process was performed. During this process, supplemental information was obtained in order to select the most appropriate answer. In this study, the terminology referring to the composition of the regions and the three-letter country codes are as designated by the United Nations (United Nations Statistical Division [UNSD], 2008).

Results and Discussion

Metrics of Survey Response

Of the 33 countries surveyed, responses were received from 24 (73%); however, information from supplemen-

Table 1. Survey response in the various sub-regions in LAC.

Sub-region	Number of countries surveyed	Number of surveys returned (%)	Countries for whom no survey forms were returned, but for whom information was achieved by other means
Central America	8	21 (43)	NIC
South America	12	41 (27)	-
The Caribbean	13	8 (18)	Antigua and Barbuda (ATG), Bahamas (BHS), Barbados (BRB), Dominica (DMA), Saint Kitts and Nevis (KNA), VCT

tal sources allowed 31 countries (94%) to be described in the study. Table 1 shows the number of survey forms sent and returned by each of the LAC sub-regions, as well as non-respondent countries for which information was achieved by other means. The Caribbean was the sub-region with the lowest response rate (see Table 1), demonstrating either a lack of competency in the particular aspects where information was requested or a lack of personnel regularly engaged in biosafety to be able to answer the survey. Additionally, there was a paucity of informed stakeholders from the Caribbean and the Central America regions, as compared to South America. This is presumably due to the fact that South American stakeholders attend more international meetings, publish more peer-reviewed articles, and tend to be more involved or engaged with international organizations.

The number of surveys returned per country was generally low (Table 1). Out of the 300 contacts in the database, the survey was successfully received by 244, since not all of the compiled contact details were valid or current. On average, only 27% of the contacts responded. Nevertheless, even if for many countries there were few respondents (1-3), some were key stakeholders able to provide useful information (e.g., members of national biosafety committees [NBCs] or NCAs). Moreover, a 27% response rate is typical of such surveys, which average around 20% (Kelley, Clark, Brown & Sitzia, 2003). One of the major factors limiting the amount of response from particular countries was the difficulty in obtaining current email addresses for pertinent stakeholders—a symptom of either their lack of dependence upon the Internet, or the lack of sufficient levels of connectivity to facilitate this method of correspondence.

rDNA Biotechnology R&D

The adoption of rDNA biotechnology in the LAC region has increased in recent years (Organization for Economic Co-operation and Development [OECD], 2009). Stein and Rodríguez-Cerezo (2010) expect that about 50% of the new transgenic events capable of being brought to market by 2015 are most likely to be developed in Asia and Latin America, with the remainder by the transnational private seed sector in the United States and the European Union. To date, the results of the study show that at least 13 LAC countries (Argentina [ARG], Brazil [BRA], Chile [CHL], Colombia [COL], Costa Rica [CRI], Cuba [CUB], Guatemala [GTM], Guyana [GUY], Jamaica [JAM], Mexico [MEX], Peru [PER], Trinidad and Tobago [TTO], and Uruguay [URY]) are or have been engaged in the domestic[2] development of GMOs and have carried out laboratory and/or glasshouse-based research for this purpose. Fifteen countries (ARG, BRA, Bolivia [BOL], CHL, COL, CRI, CUB, Honduras [HON], JAM, MEX, Panama [PAN], Paraguay [PRY], El Salvador [SLV], TTO, and URY) have approved confined field trials (CFTs) of GM crops in their territory. However, only 9 (ARG, BRA, CHL, COL, CRI, CUB, JAM, MEX, and TTO) out of the 15 countries are currently performing CFTs for locally-developed products. Commercial activities with GM crops in the LAC region have mainly involved products developed outside the region. However, the Brazilian Agricultural Research Corporation (EMBRAPA) has recently received approval from the Technical Commission on Biosafety (CTNBio) to commercially cultivate locally-developed golden yellow mosaic virus-resistant GM beans, and is currently registering the product. Developers in Brazil are expecting to receive commercial approvals of other domestically-developed products such as sugarcane. Currently, at least 38 domestic GM products are at various stages of development in LAC, ranging from laboratory research to CFTs and also commercialization. Many of these products involve improvements of major crops (e.g., papaya, maize, rice), as well as other organisms such as micro-organisms, cattle, and vaccines. Overall, Argentina appears at the forefront of domestic GM product development within the region. However, at the South American sub-regional

2. *This signifies products that have been locally developed by native institutions or companies. They should not be confused with products developed elsewhere but used or reproduced in the LAC region.*

level, Argentina is quickly followed by Brazil, Chile, and Colombia. Mexico and Costa Rica have developed the most GMOs in the Central American sub-region, while Honduras has approved several GMOs of a non-domestic origin (e.g., products from transnational companies). In the Caribbean, Cuba is clearly taking the lead, followed by Jamaica and Trinidad and Tobago, with a greater laboratory capability than many of its neighbors (United States Department of Agriculture [USDA], 2008). Focussing on Cuba, sources indicated that the work of current projects is aimed at transferring resistances to crop pest insects and infecting viruses and/or herbicide tolerance to a wide range of crops, including banana, maize, papaya, plantain, potato, rice, sweet potato, and tomato. Successful products from these projects are expected to be offered directly to Cuban farmers (Carboni, 2006). Despite the efforts in rDNA biotechnology R&D of a select few countries, the situation in LAC is similar to that in Asia, where many GM crops and other products have been developed by the public sector but have yet to achieve commercial status and be available to local producers (Falck-Zepeda et al., 2009). A possible limiting factor to this technology transfer may be insufficient budgets to complete product development and local regulatory procedures, with their inherent high costs in compiling the necessary data package for submission (Trigo, Falck-Zepeda & Falconi, 2010). Likewise, a general lack of financial support for R&D activities and the enacting of very restrictive legislations are additional factors hindering the domestic development of GMOs (Adenle, 2011).

Overall, GM maize, soybean, and cotton are the main GM products authorized in the LAC region (either for confinement and/or commercial release purposes), whereas domestic R&D attention is focused primarily on maize, papaya, potato, rice, and sugarcane, amongst others. The concentration of biotechnology activities on these crops is presumably due to their importance as local sources of food, their key roles in the economies of many countries in the region, and the magnitude of socio-cultural values associated with them. Sugarcane in particular is increasing its attractiveness to local developers and farmers, mainly due to it serving additional, high-value purposes (e.g., food source, alcohol consumption, and biofuel production). Likewise, crops such as banana, cassava, eucalyptus, plantain, soybean, and wheat are also gaining in attractiveness for local GM development. Local investment in the development or improvement of crops of national/regional interest brings new opportunities for the region in terms of agricultural autonomy; however, it also stimulates a greater division of research funds, which eventually leads to reduced amounts of money for each research project that ultimately limits the possibilities of commercialization of those crops and/or products (Trigo et al., 2010). Although the application of rDNA biotechnology in the majority of LAC countries is mainly focused on agriculture, some countries are also investigating how it may help improve the health of humans and animals, as well as increasing productivity in other areas such as aquaculture. For example, Argentina is developing GM cattle that produce therapeutic proteins (e.g., human growth hormone) in milk and Panama is already undertaking CFTs of GM salmon.

The situation of agricultural biotechnology in the LAC region can therefore be summarized as follows. First, the region has a significant level of research capacity primarily in a wide range of crop and livestock GM products. Nevertheless, this capacity is limited by restrictive funding and ineffective regulations. Second, in terms of commercial applications, domestic GM products are still at a very early stage of development, since the majority of the locally-approved commercial GM products have been developed outside of the region (Trigo et al., 2002; current study). In LAC, the involvement of the private sector in agricultural research is higher than in Africa and the Middle East, but lower than in some countries of the Asia-Pacific Region (Stads & Beintema, 2009). On the other hand, the involvement of the public sector in domestic R&D in LAC is higher than that of local private companies. According to Falck-Zepeda et al. (2009) and Adenle (2011), one of the major reasons for this may be the low level of effective protection of intellectual property in LAC countries. Nonetheless, the effectiveness of R&D activities in the private sector is notably higher than in the public sector. According to Trigo et al. (2010), approximately 80% of CFT applications presented to local authorities come from the private sector; with only an estimated 5% coming from public-sector activities. This situation prevents many indigenous/domestic developments from being available to the public. In other words, although R&D capacity in LAC may be present, the region experiences technology transfer constraints.

Biosafety Regulatory Experience in the LAC Region

In general, the study showed that the region is very heterogeneous in terms of biosafety proficiency, and as such, there has been no consensus at the regional level on how best to respond to global developments in

genetic engineering and, particularly, whether to permit the importation and/or development of GM products. Many countries are still lacking operational regulatory systems (defined as: legislation + regulation + established NCAs and NBCs) and sufficient biosafety proficiency to assess new rDNA biotechnology applications. Elements that may be restricting or obstructing the development of such regulatory systems include the high costs associated with establishing institutional networks for risk evaluation and the insufficiency of analytical capacities in technical disciplines (e.g., biology, ecology, and socio-economics), in part due to a lack of local expertise (Trigo et al., 2002). Likewise, there is a lack of proper coordination and harmonization for developing biosafety regulation in developing countries, resulting in a slowing-down of GMO decision-making processes (Adenle, 2011). Also, another limiting factor is that even when technically competent personnel such as researchers, agronomists, molecular biologists, etc., are present, they are not always in a position to sacrifice portions of their working hours (e.g., in research or academic activities) to work on or support the biosafety regulation process—itself a very demanding and time-consuming activity. Moreover, biosafety regulatory institutions in the region are often *ad hoc* extensions of pre-existing institutions formed with agricultural, environmental, or health purviews; this is a situation that at times can restrict the development of independent biosafety capacities. This, coupled with the lack of specific funding for actions such as payment of salaries, data acquisition, procurement of instruments, etc., prevents competent personnel from becoming permanently engaged in biosafety regulation.

In the LAC region, 85% of countries are parties of the CPB, and 79% have already developed biosafety frameworks. However, our study found that only 58% of the countries (for which information was obtained) have an operational biosafety regulatory system in place. Moreover, due to differing interests in biotechnology applications, not all of the countries with operational regulatory systems have experience to the same extent; for example, some have only processed CFT applications to date, whereas a few others have also authorized open cultivation. Other aspects contributing to the heterogeneity of biotechnology regulation in LAC include the diversity of the political perspectives in the region and the extent to which each country makes use of the technology (Trigo et al., 2010). Therefore, with the aim of facilitating future capacity-building initiatives in the region, countries have been categorized in this study based on their biosafety expertise in GMO utilization (e.g., growing and monitoring activities), and GMO authorization process (for various purposes); thus, Category A=laboratory and glasshouse (contained) research, Category B=confined field trials, Category C=commercial cultivation, and Category D=importation of GM products. For example, as shown in Figure 1, countries that have experience with the management of GMOs in all 4 categories (ARG, BRA, COL, CUB, Honduras [HON], MEX, and URY) have greater biosafety regulatory expertise than those countries which have authorized activities in only one of the categories. These criteria are clearly not the only factors that may be used to measure the biosafety expertise of a country; however, the rationale behind their selection is that a country truly only generates indigenous regulatory experience when it has gone through the process on its own (authorization) and when it has put into practice the technical and scientific information or knowledge it possesses (utilization).

To date, GMOs have been authorized in these different categories in 19 countries. Nine of these 19 countries are in the South American sub-region (ARG, BOL, BRA, CHL, COL, GUY, PER, PRY, and URY), denoting this territory as the most active with respect to GMO regulation. Moreover, this sub-region includes the largest number of countries in LAC authorizing GMOs for commercial use, contrasting sharply with the situation in the other sub-regions. In Central America, the study showed that 6 countries (CRI, Guatemala [GTM], HON, MEX, PAN, and SLV) have also authorized GMOs for multiple purposes. However, other sources indicated that Nicaragua (NIC) should also be included in this list (USDA, 2009a). Mexico is clearly the most advanced country in terms of regulatory experience in the sub-region, followed by Honduras and Costa Rica. The remaining countries have limited experience, mainly in categories A, B, and/or D (Figure 1). Regulatory experience in Panama is unique since this country has recently approved applications for field trials of GM mosquitoes and GM salmon, thus becoming the first country in Central America to authorize CFTs of a GM animal. The Caribbean sub-region as a whole is beginning to address the need for a regulatory regime in biosafety. With the exception of Cuba (with its mature and experienced regulatory system), many islands are currently developing comprehensive biosafety policies and enacting legislation to this effect. Nevertheless, it will still be some time before these regulatory mechanisms will be functional. In recognition of this, the Caribbean Community and Common Market (CARICOM) is now heading a serious effort to harmonize biosafety policies in the sub-region

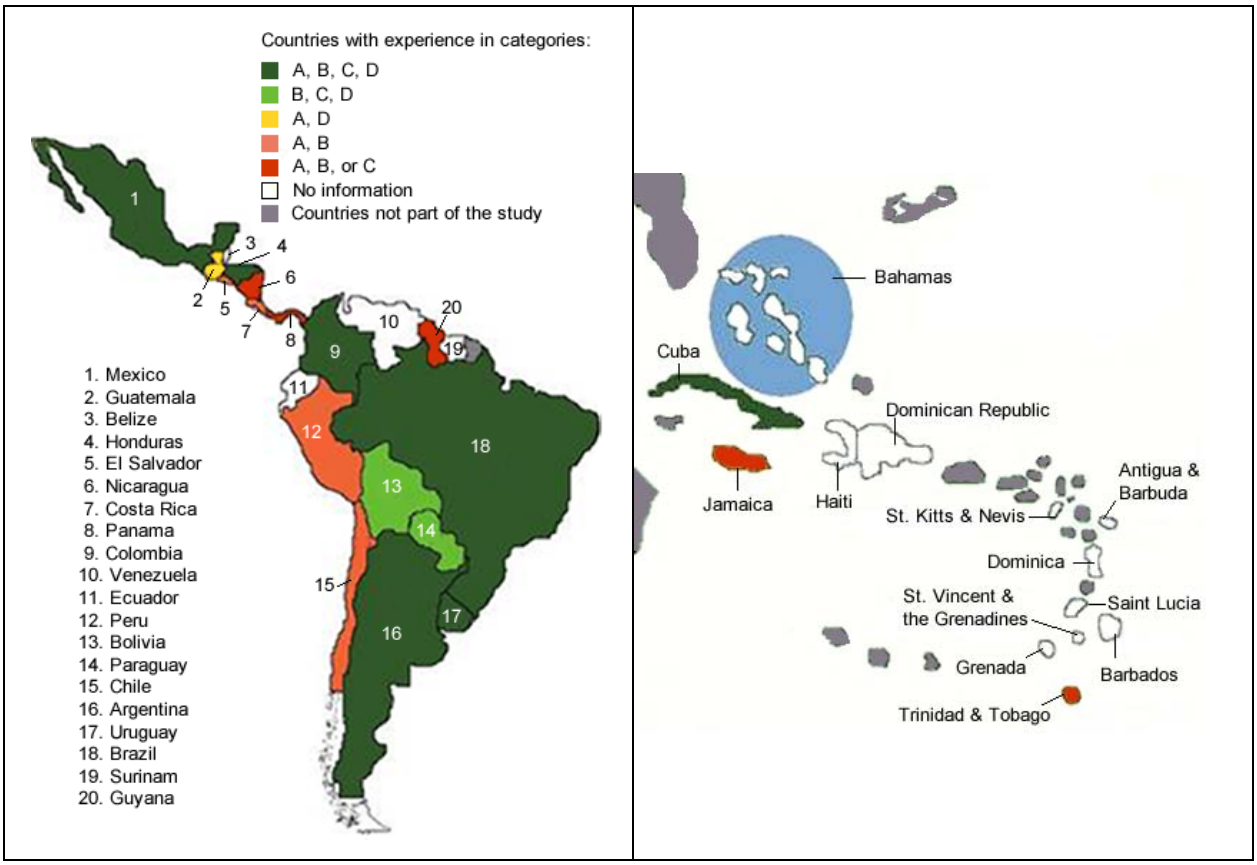

Figure 1. Biosafety regulatory experience in the LAC region according to the assessment of applications and process taken place in each country.

Note. Data compiled from: ICGEB LAC survey 2009-2011, Salazar and Montenegro (2009); USDA (2009a, 2009b); and Roca, Espinoza, and Panta (2004). Maps not to scale. Categories: A=regulating contained (laboratory & glasshouse) research; B=regulating confined field trial releases; C=regulating unconfined (commercial) releases; D=regulating the importation of GM products.

to ensure an adequate balance between biosafety and biotechnology development and trade (USDA, 2008) without subjugating or replacing national laws.

The regulatory situation and experience in the region is obviously not static, and many countries are currently making efforts to improve their regulatory capacity. Our study showed that 87% of the countries are currently involved in developing biosafety legal instruments (e.g., biosafety law/regulation, normative updates, technical norms, guidelines, etc.), thereby allowing the assessment of biotechnology applications in the near future. These instruments are being developed either in countries where a legal instrument is already in place or in those in which the first legal biosafety instrument is being developed, such as in the case of Grenada (GRD), Paraguay, Saint Lucia (LCA), and Trinidad and Tobago. For those countries currently active in both rDNA biotechnology and the development of biosafety legal instruments, pre-existing legislation (i.e., laws governing phytosanitary protection, food and human health, and environmental and natural resources) is being used during the interim period. Capacity-building initiatives aiming to provide biosafety support in the region should take into account the differences in experience amongst countries (Araya-Quesada et al., 2010), as it is clear that some countries require a deeper and more multidisciplinary intervention in order to address biosafety regulatory needs (e.g., the development of a biosafety law), while others need only minor inputs to provide them with key instruments (e.g., specific guidelines) to allow a more efficient operation of the systems that are already in place.

Public Participation and Socio-economic Considerations in LAC Regulatory Systems

The social and economic issues related to rDNA biotechnology are many, and there are a number of gover-

nance strategies and regulatory tools that can be employed to address them (Fransen et al., 2005). However, introduction of socio-economic considerations into the risk analysis of GMOs is still controversial (Falck-Zepeda, 2009), as there is no consensus on what to include nor how they should be addressed.

Many LAC countries believe it important to include socio-economic considerations in biosafety decision-making. For example, 17 countries (BRA, BOL, COL, CUB, Ecuador [ECU], GRD, GTM, GUY, JAM, LCA, MEX, PAN, PRY, SLV, TTO, URY, and Venezuela [VEN]) take specific socio-economic considerations into account in their regulatory processes, either through cost-benefit analysis assessing yield and production cost differences between conventional and GM agricultural practices, or analysis based on the impact that these products might have on their markets (e.g., export and domestic consumption). However, the reality is that the majority of LAC countries still exhibit the general need of how to effectively include these considerations into actual decision-making. Moreover, the inclusion of socio-economic considerations is gaining importance for many countries in the region, since previous risk analyses have focused entirely on possible consequences to the environment and human health, omitting other important issues such as the possible benefits or impacts on local farmers, the general public, and domestic economies. The need to clearly define the 'how,' 'when,' and 'under what rules or circumstances' decision makers will consider socio-economic issues increases their relevance in the risk-analysis process (Falck-Zepeda, 2009). In other words, the need to create an objective method, able to capture all the factors that are useful for the risk analysis should not be minimized. Further, Falck-Zepeda (2009) also highlights the importance of considering the extensive time and costs incurred to demonstrate safety; long and costly regulatory processes may constitute a disincentive to local R&D, especially for the public sector that may be developing public goods and often relying on limited budgets. And lastly, as much as it is important to account for socio-economic considerations associated with the use of rDNA biotechnology, it is of equal importance to assess the possible consequences of not using the technology.

While some socio-economic considerations can be dealt with directly by biosafety regulations or policies, others (e.g., the focus of research activities, the local importance of specific products) could be also addressed through other means, such as guidelines for scientific institutions or national laws not specifically related to biotechnology (Fransen et al., 2005). However, many factors still hinder the incorporation of these considerations in LAC, such as the absence of technical capacity and institutional coordination. Additionally, challenges related with political issues, inconsistency between organizations, and governmental departmental coordination will confront any country willing to address socio-economic considerations (Secretariat of the CBD, 2010). Regarding public participation, its integration into decision-making is an important step towards the good governance of rDNA biotechnology. For example, it may help to identify and resolve socio-economic concerns (Fransen et al., 2005). To date in the LAC region, 15 countries (ARG, BRA, COL, CRI, ECU, GRD, GUY, LCA, MEX, PAN, PER, PRY, SLV, TTO, and URY) stated that public consultations are performed before making any decision relative to the authorization of GMOs. Nevertheless, in the majority of the cases, public participation mechanisms and the role they play have been poor or limited, resulting in little interaction between regulators and decision makers with the general public. Consequently, mechanisms to ensure effective participation should be commensurate with local conditions, and be part of responsible risk communication. This will promote better-informed involvement by the public, based on sound scientific data and proven facts instead of—at times—biased media coverage. The role of media in the public acceptance and/or rejection of GMOs is of great importance. Most media coverage in developing countries has been incomplete on the subject of GMOs, mostly due to a lack of analytical reporting and poorly-informed debate (Adenle, 2011).

Access to Previous Training Opportunities and Current Training Needs

With the aim of identifying gaps in the technical expertise of NCA personnel, information was sought regarding the competency of members in the following areas: environment, health, agriculture, legislation, and/or regulation. The consultation confirmed that many NCAs had expertise in all of the above-mentioned fields, such as in ARG, BRA, Belize (BLZ), BOL, COL, CUB, Dominican Republic (DOM), GTM, HON, JAM, MEX, PAN, PRY, SLV, TTO, URY, and Venezuela (VEN), thereby representing those regulatory systems most capable of assessing the possible impacts of a broad discipline such as rDNA biotechnology. Nevertheless, having a scientific background in one or more of the above-mentioned areas does not necessarily imply having pro-

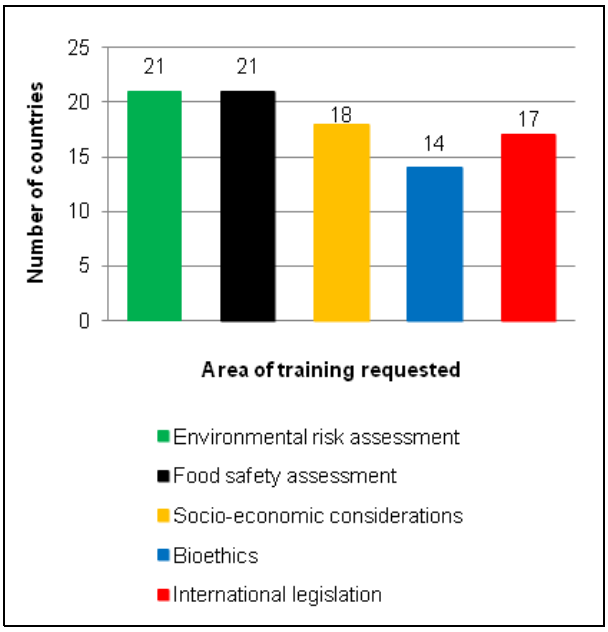

Figure 2. Training requests by survey respondents considered necessary for NCA's personnel.
Note. Data from ICGEB LAC survey 2009-2011.

ficiency in the biosafety of GMOs. Local opportunities for receiving specific biosafety training are scarce and therefore, NCAs rely on scientists of related disciplines. However, there are a few NCA representatives in LAC who have received biosafety training at the national or international level, in areas such as biosafety legislation and regulation, GMO detection methods, implementation of Biosafety Clearing House (BCH) systems, risk analysis, etc. Some countries are multiple recipients of these training opportunities, as in the case of Argentina, Costa Rica, Mexico, and Paraguay, for example. However, all countries acknowledged the need to receive further technical training (Figure 2). The training received by the NCAs was offered by a vast range of institutions, such as the Genøk-Centre for Biosafety (Norway), the Instituto Tecnologico de Costa Rica, the International Centre for Genetic Engineering and Biotechnology (ICGEB), Michigan State University (United States), the Secretariat of the Convention on Biological Diversity, the US Department of Agriculture (USDA), the Universidad de Buenos Aires (Argentina), and the Universidad Nacional Agraria de La Molina (Peru), amongst others.

The study also captured locally-identified specific training needs in the LAC region. Overall, these included the need to develop approaches for the evaluation of: the possible consequences of the use of GMOs in centers of origin, gene flow from GM crops to native species, allergenicity and toxicity potential, the role of substantial equivalence in risk assessment, possible impacts on local farmers, socio-economic impacts, and bioethics. Capacity builders offering support in these particular topics are therefore better placed to fill these gaps. However, for support to be effective, building capacity and transferring knowledge should be aligned with prevailing local conditions. Although developing countries may share a set of similar biosafety needs, they may also exhibit regional variation (Araya-Quesada et al., 2010). For instance, in some cases, training is required at several levels in order to assist biosafety regulatory systems to become fully functional (e.g., BLZ, DOM, GUY, LCA, and Saint Vincent and the Grenadines [VCT]), while in other cases, it is only needed to improve the performance of systems that are already operational (e.g., ARG, CRI, CUB, MEX, and URY). The study identified short courses (e.g., one- or two-week training workshops) and study abroad as the types of training most preferred by respondents, followed by long-term courses (e.g., 1- or 2-year Master of Science programs) and studies offered locally. Additionally, the recognition of "technical, social, or economical" gaps in the region will clearly impact future interventions towards biosafety proficiency. For instance, 19 countries (ARG, BOL, BRA, COL, CRI, CUB, DOM, Ecuador [ECU], GRD, GTM, JAM, MEX, PAN, PER, PRY, SLV, TTO, URY, and VEN) stated "financial constraints" as the key factor restricting NCA members from taking training opportunities, while 11 other countries (CRI, CUB, DOM, ECU, GTM, MEX, PAN, PER, PRY, SLV, and URY) also indicated the "lack of local experts able to be involved in biosafety activities" as a major limiting factor.

Finally, since biotechnology and genetic engineering are continually evolving, there is a constant need to train and educate not only new NCA members (due to the high turnover of experts and staff employed) but also to update current staff in the latest approaches and techniques. For example, biosafety training given to members of NCAs focusing on the possible consequences of releasing herbicide-tolerant and/or insect-resistant crops into the environment—although relevant in the region—is not sufficient for the new wave of GM crops being developed with traits such as stress tolerance or biofortification. Thus, there is a need for training stakeholders to also be updated.

The Legacy of Previous Capacity-building Programs in the Region

Over the last decade, international assistance through numerous capacity-building programs has played an increasingly important role in assisting developing countries to sharpen their biotechnological capacities and to respond to biosafety concerns, the cost of which has totalled more than US$135 million (Johnston et al., 2008).

A review of previous initiatives in the LAC region revealed activities in a range of areas, such as, *inter alia*, technical training, the application of plant biotechnology, and public awareness. The visible outcomes of these efforts have mainly been in the development of the numerous national biosafety policies, frameworks, and legislative and regulatory instruments (draft and/or final) published in the region (USDA, 2005; World Bank, 2008). However, other projects have also supported R&D in agricultural biotechnology, such as those funded by the Consultative Group on International Agricultural Research (CGIAR) and the Rockefeller Foundation (Johnston et al., 2008). Regarding the support towards the development of biosafety policies and regulations, it is important to highlight that these instruments may not be effectively implemented if they are not linked to the adequate training of personnel. As such, it is essential that capacity builders target not only the development of regulatory instruments, but also the (novice) regulators charged with enabling them.

The project implemented by the United Nations Environment Programme (UNEP) and funded by the Global Environment Facility (GEF) aimed at the development of national biosafety frameworks has had a significant impact in the drafting of biosafety policies in the region as a starting point for the further development of national biosafety laws and guidelines. Similarly, the UNEP-GEF BCH project has made remarkable in-roads in many countries in facilitating access to biosafety information and helping parties of the CPB in its implementation. Complementary capacity-building activities have either been funded, implemented, or both by a range of prominent actors, and are assisting countries in the region to deal with the challenges from the use of rDNA biotechnology. For instance, with a view towards regional cooperation, the United Nations University-Programme for Biotechnology in LAC (UNU-BIOLAC) has developed a South-South network strategy by which some LAC countries receive advice from more-experienced neighbors such as ARG, BRA, CHL, and URY (Ramirez, 2003). Along the same lines, ICGEB and the Academy of Sciences for the Developing World (TWAS) collaborated in the "Plant Biotechnology Program" with the aim of strengthening South-South collaboration amongst scientists and building capacity in plant biotechnology in countries where this type of activity is poorly represented. The Food and Agriculture Organization of the UN (FAO) has also provided technical assistance to enhance legislative frameworks in several LAC countries (e.g., ARG, BRA, BOL, CHL, DOM, GRD, NIC, PRY, and URY; FAO, 2009; USDA, 2005), while the UN Industrial Development Organization (UNIDO) coordinates a distance-learning Master of Science degree program in the biosafety of plant biotechnology. The Electronic Forum on Biotechnology in Food and Agriculture,[3] hosted by FAO, is another example of a capacity building initiative that has stimulated the dissemination of information and public awareness in key biosafety topics (FAO-Biotechnology Forum, 2009; USDA, 2005).

Activities by regional actors—for example, La Red de Cooperación Técnica en Biotecnología Vegetal (REDBIO/FAO), the CARICOM committee within the Caribbean Agricultural Research and Development Institute (CARDI), the multi-country capacity-building project for compliance with the CPB (MC-CBP [LAC-Biosafety]),[4] and the Hemispheric Biotechnology and Biosafety Program (HBBP) of the Inter-American Institute for Cooperation on Agriculture (IICA)—are also heavily influential. The REDBIO network links more than 5,000 researchers from 738 labs within 32 countries in the region with the aim of accelerating the process, generation, transfer, and application of plant biotechnology to contribute to the solution of crop production constraints and genetic resource conservation for the countries in LAC (USDA, 2005). REDBIO also promotes information-sharing and capacity-building activities (Ortiz, 2010). In the case of CARICOM, the committee reviewed all of the national biotechnology policies with a view towards eventual harmonization (USDA, 2008). The LAC-Biosafety project implemented by the World Bank benefits Brazil, Colombia, Costa Rica, and Peru (all mega-diverse countries) and is oriented towards improving knowledge generation for biosafety risk assessment, risk management, and decision-making (World Bank, 2008). Likewise, the HBBP is facilitating mechanisms for the development, management, and responsible use of agro-biotechnology in

3. http://www.fao.org/biotech/biotech-forum/forum-home/en/

4. http://www.lacbio.org

promoting competitive and sustainable agriculture in the region (IICA, 2007).

In summary, there are many institutions providing biosafety support in the LAC region and covering a wide range of areas. Nevertheless, the region still requires a great deal of support for overall biosafety proficiency to be achieved. Assistance to these countries should be enhanced and strategically planned. Areas such as the protection of intellectual property rights, improving technical and scientific knowledge, risk communication, and understanding socio-economic implications still remain key needs and represent targets for future capacity-building initiatives to provide assistance.

Conclusions

The potential application of rDNA biotechnology to living natural resources in developing countries is enormous, not only because developing countries contain more than 70% of the world's agricultural and forest land, but also because agriculture is extremely important to their economies (OECD, 2009). Despite the fact that some LAC countries are already developing GMOs and have regulatory systems in place, the region as a whole is generally lacking in the technical capacity to carry out domestic rDNA biotechnology R&D on a large scale and to implement operational, cost-/time-effective, and self-sufficient regulatory systems. Similarly, there is a specific need for the permanent participation of scientifically-trained personnel in regulatory processes, coupled with improving the availability of economic resources and basic scientific information (Adenle, 2011; Falck-Zepeda et al., 2009). All these factors are essential to performing reliable risk assessments of GMOs and effective decision-making. The study identified a paucity of basic information in LAC concerning baseline agronomic data of major regional crops, the elaboration of the possible risks to centers of origin, *in situ* data of relevance to tropical conditions (e.g., field trials results from experiments performed in the tropics), etc. Additionally, GM crops with new traits (e.g., drought and salt tolerance, bio-fortification, etc.) are continually being developed and are gaining in international importance, and as such, they may present novel challenges to regulatory systems in those LAC countries where the relevant applications are to be submitted. Furthermore, some of the existing biosafety laws in the region were adopted at a time when there was less awareness and knowledge of biosafety issues, as well as only a few GM products on the market. Consequently, many laws are in need of review for completeness and to incorporate potential updates. The necessity of 'implementation documents' such as guidelines and directives also should not be underestimated, as they greatly facilitate the practical application of national biosafety laws and international agreements. As has been previously mentioned, 87% of the study countries are currently developing legal instruments, including guidelines and directives. Nevertheless, for regulatory systems to be operational, such implementation documents should also be developed (e.g., monitoring and risk-assessment guidelines, importation directives, administrative procedures, etc.), allowing countries to extend their regulation over a greater range of categories.

In the LAC region, many training opportunities have been offered (for example, in generic risk assessment and risk analysis), however few have focused on providing practical approaches towards improving efficiency in the overall decision-making process (e.g., data prioritization and evaluation coordinated via a "problem formulation"-orientated approach). The development or incorporation of more expedient methods would be of great help to LAC regulatory systems, where limitations to money and time are obstructive to effective biosafety assessments. Capacity-building efforts in GMO detection and traceability are also still much sought after. In this respect, assistance for countries to become proficient on these matters would have a tremendous impact on trade activities within the region since it would grant countries the possibility to meet international and national obligations (e.g., certify the amount of GM material contained in a product). At the same time, this will enhance scientific and political autonomy by reducing dependency on external/foreign laboratories. When addressing GMO detection needs, the possibility of regional detection laboratories/facilities should be considered. This could represent a more effective strategy, in particular if economic resources are insufficient to provide each country with their own facility. In addition, according to the Caribbean Basin Agricultural Trade Office (CBATO), the Caribbean sub-region is in need of training for their inspection services (USDA, 2008), as these are currently only being provided with support from FAO (FAO, 2009). As such, there is ample opportunity for capacity-building initiatives to either complement one another or join efforts. Such approaches would be underpinned if countries in the region could work together to define common strategies to deal with joint funding and execution of biosafety matters, especially when situations are of a trans-boundary nature (Trigo et al., 2002).

In the LAC region, capacity builders aiming to provide support in the above matters will face challenges such as the lack of institutional infrastructure, the lack of biosafety and intellectual property rights (IPR), institutions with limited operational capacity (e.g., lack of expertise and or personnel), and weak technology delivery systems (Trigo et al., 2002). Adding to these is the immaturity of many of the regulatory systems and NCAs in the region. On the other hand, if support is to promote R&D in rDNA biotechnology by the public sector, then more studies to clarify the role of intellectual property rights in local policies and regulations must be carried out (Falck-Zepeda et al., 2009).

Overall, the diversity of concerns related to GMOs proves that there is not one single aspect that triggers the development of biosafety measures and their application in LAC countries, but many; thus, any capacity-building initiative aiming to provide assistance must consider a multidisciplinary approach. Duplication of efforts in providing training and/or support to the same stakeholders, as well as in the same topics, must be avoided if a full autonomy in biosafety decision-making is desired for the region. Moreover, any attempt to provide support should be tailor-made, only requiring resources that are within the means of beneficiary countries (e.g., infrastructure, technical analysis, number of personnel, timeframes, etc.) instead of replicating other regulatory frameworks designed to serve developed countries' needs. South-South cooperation is also advisable in combination with North-South cooperation approaches, since it will offer expertise in addressing potential locally-important issues.

Finally, cooperation amongst capacity builders is a logical strategy to pursue in addressing biosafety needs since it allows the various and different expertises and knowledge available to interact and complement one another, offering a wider range of opportunities for the relevant stakeholders (Araya-Quesada et al., 2010) in the LAC region.

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